

CCMO: CTIS Tips and Tricks

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Trial category and relevant document publication timelines

Trial category and relevant document disclosure timelines

1. Determine which category is applicable for the trial. This is dependent on the trial type.

Category	Trial type
Category 1 Pharmaceutical development clinical trials	Phase I clinical trials in healthy volunteers or patients Phase 0 trial in healthy volunteers or patients Bioequivalence and bioavailability trials Similarity trials for biosimilars Equivalence trials for combination or topical products
Category 2 Therapeutic exploratory & confirmatory clinical trials	Phase I and phase II integrated clinical trials Phase II clinical trials Phase II and phase III integrated clinical trials Phase III clinical trials
Category 3 Therapeutic use clinical trials	Phase III and phase IV integrated clinical trials Phase IV clinical trial and low interventional trials

2. Depending on the trial category, certain documents will become publicly accessible. See Table I and II of the [Annex I Guidance Document](#) for an overview of the published structured data and documents as well as relevant disclosure timelines. In order to protect commercially confidential information (CCI) and/or personal data, a document with redactions (“**For Publication**”) and a document without redactions (“**Not for Publication**”) can be uploaded in CTIS. Documents not in this list will not be publicly accessible. For more information, see the [Revised CTIS transparency rules](#).

Table II – CTIS Documents ‘for publication’ and relevant disclosure timelines

The detailed list of documents that are, or are not subject to publication is specified in documents on [CTIS application fields](#) and [Notification and Results](#). Disclosure timelines are provided in this table, and modalities in table IV (including exceptions applicable to ‘historical trials’).

Caution: any document inadvertently uploaded ‘for publication’ into the below document upload sections will be published. Example: if an IB is uploaded into the SmPC section of a Cat 2 or 3 trial, the IB will be made public if not corrected by the sponsor before the decision on the application.

Documents ⁴ <i>to be submitted in two versions 'for publication' and 'not for publication'</i>	Publication timelines ⁵		
	Category 1	Category 2 and 3 <i>including integrated ph1&2</i>	
	Paediatrics and/or PIP	Adults	
Protocol, including patients facing documents ⁶	Upon results' submission	30 months after EU/EEA EoT	First MSC decision
Protocol synopsis			
SmPC, if available	Never		That MSC decision
Recruitment arrangements, including procedures for inclusion and copy of advertising material ⁷			
Subject information and informed consent form			
Lay person summary of results	As soon as submitted	30 months after EU/EEA EoT	As soon as submitted
Final summary of results ⁸			
Clinical study report, if available ⁹	As soon as submitted		

⁴ Table III lists the type of personal data generally contained in documents ‘for publication’, while for an indicative list of documents that are not published: see table VI

⁵ To know the type of trials belonging to each Category, refer to table V

⁶ Protocol: this is referred to any kind of protocol (including master protocol, sub-protocol, etc.); patients facing documents: see definition in [Clinical Trial Regulation 536/2014 Q&A](#)

⁷ Recruitment arrangements: provide a clear indication of what the first act of recruitment is; advertising material: this includes any printed materials and audio or visual recordings

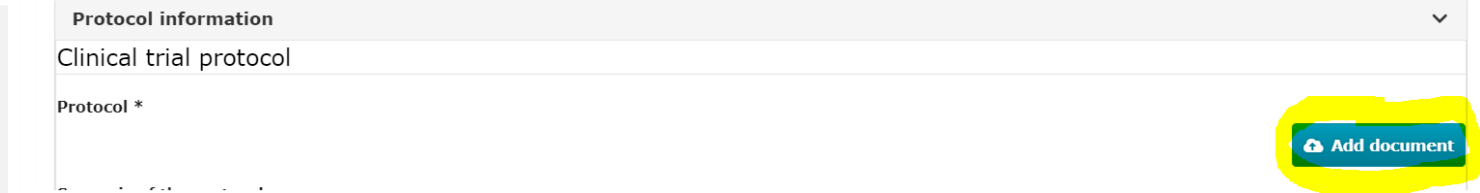
⁸ Interim results are not made publicly available; only final summary of results are; these documents are distinguished through a dropdown menu of the relevant stakeholders

How to **Upload** a Document in CTIS

“For Publication” and “Not For Publication” Documents

Uploading Documents: For Publication and Not for Publication

1. Click on “Add document”.



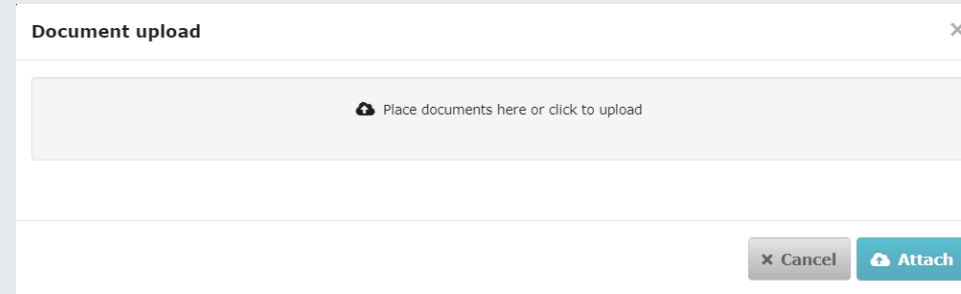
Protocol information

Clinical trial protocol

Protocol *

Add document

2. Drag or upload the document to CTIS.
Always add the document intended for publication (with redactions) to CTIS first.



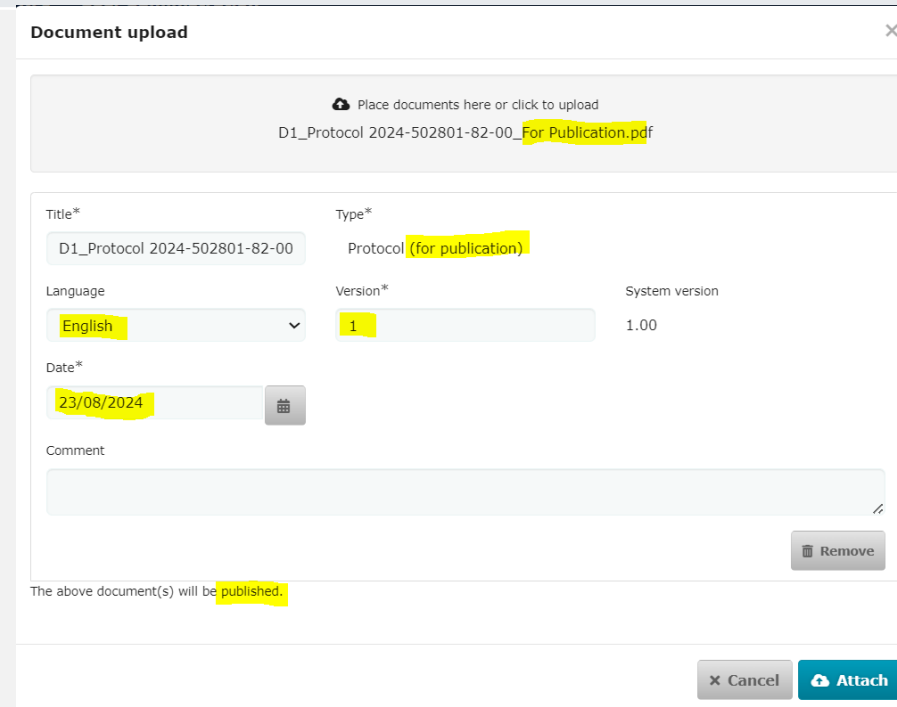
Document upload

Place documents here or click to upload

Cancel Attach

3. Check that the document intended for publication is uploaded in the “For Publication” placeholder. If needed, update the document title to comply with the [CTCG best practice guide naming of documents](#)).

Update the language, version and date. The language, version and date inputted into CTIS should match the language, version and date in the document itself.
Then click Attach.



Document upload

Place documents here or click to upload

D1_Protocol 2024-502801-82-00_For Publication.pdf

Title* D1_Protocol 2024-502801-82-00 Type* Protocol (for publication)

Language English Version* 1 System version 1.00

Date* 23/08/2024

Comment

Remove

The above document(s) will be published.

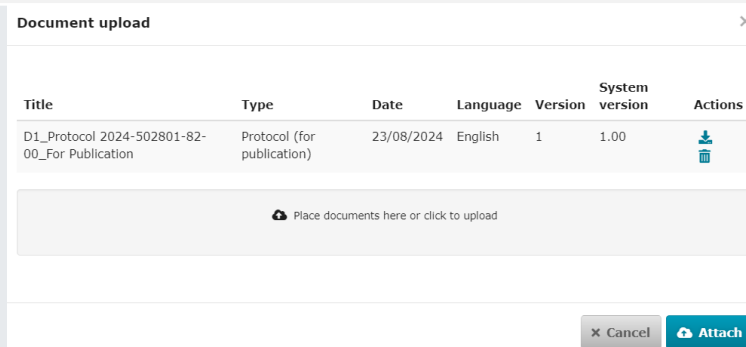
Cancel Attach

Uploading Documents: For Publication and Not for Publication CONTINUED...

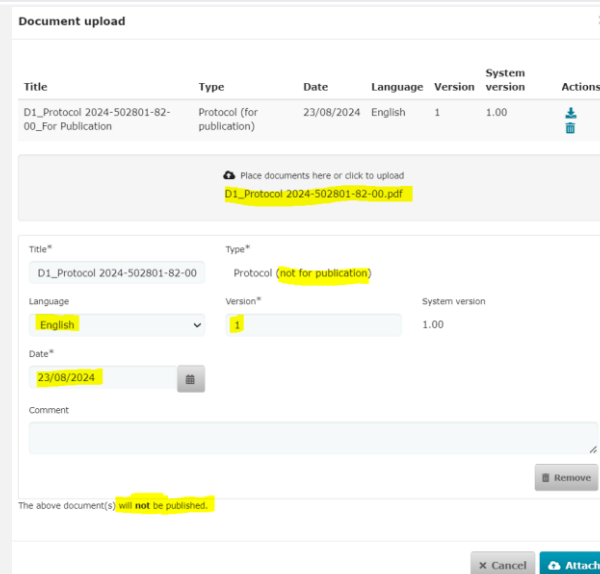
4. To upload the “Not for Publication” version of the same document, click on (+ Add) icon found next to the “For Publication” version of the document.



5. Drag or upload the document to CTIS. This time, add the “Not For Publication” version (without redactions) to CTIS. Please note, the “Not For Publication” version is not required if there are no redactions in the “For Publication” version.



6. Check that the document intended as not for publication is uploaded in the “Not For Publication” placeholder. If needed, update the document title to comply with the [CTCG best practice guide naming of documents](#)). Update the language, version and date. The language, version and date inputted into CTIS should match the language, version and date in the document itself. Then click attach.



How to **Upload** a Document in CTIS

Documents not publicly accessible

Uploading Documents: Not Publicly Accessible

1. Click on “Add document”.

Data safety monitoring committee charter

Add document

2. Drag or upload the document to CTIS.
This document will not be publicly accessible so only a version without redactions is required.

Document upload

Place documents here or click to upload

Cancel

Attach

3. Check that the document is uploaded in a placeholder that will not be publicly accessible. If needed, update the document title to comply with the [CTCG best practice guide naming of documents](#)).

Update the language, version and date. The language, version and date inputted into CTIS should match the language, version and date in the document itself.
Then click Attach.

Document upload

Place documents here or click to upload

D3_DSMB Charter 2024-502799-38-00.pdf

Title*

D3_DSMB Charter 2024-502799-

Type*

Data Safety Monitoring Board Charter

Language

English

Version*

1

System version

1.00

Date*

23/08/2024

Comment

Remove

This document will not be publicly accessible.

Cancel

Attach

How to **Update** a Document in CTIS

Updating Documents

1. Click on the symbol ( Update) found next to the previous “For Publication” version of the document. This will allow you to update the “For Publication” version of the document.

2. Drag or upload the document to CTIS. The name of the previous document will remain the name of the new document.

Update the version and date. The version and date inputted into CTIS should match the version and date in the document itself.

Then click update.

Protocol information

Clinical trial protocol

Protocol *

 D1_Protocol redacted



English · Protocol (for publication) · System version 1.00
submission date 13/08/2024
· Version 1 · 13/08/2024

Add document

Document upload

Place documents here or click to upload

D1_Protocol 2024-502801-82-00 For Publication.pdf

Title

D1_Protocol redacted

Type

Protocol (for publication)

Language

English

Version*

2

Date*

13/08/2024

Comment

SM-1

Cancel

Update

3. Follow the same instructions for the “Not for Publication” version of the document as well as for the documents that are not publicly accessible. When updating redacted documents that are publicly accessible (such as the protocol or ICF), remember to update and upload both the “For Publication” and “Not for Publication” versions.

RFI instructions

Applying changes and submitting the RFI Response

RFI instructions for sponsors

1. Navigate to the RFI in the Evaluation section, under the correct part (Validation, Part I or Part II).

Open the RFI by clicking the lock (closed lock = available for editing). Make sure to submit the RFI Response by the indicated Due Date, otherwise the application will lapse and cannot continue.

2. Scroll down to see the considerations within the RFI. Each consideration contains a lock button. After closing the lock, a textbox will appear to enter a written response, which is mandatory.

After the written response has been entered, click 'Save response', which will open the lock again. This should be repeated for each consideration.

The purpose of the optional 'Add document' button is NOT to upload the requested documents but can be used to submit the response to that particular consideration as a document. In practice, it is rarely used.

The screenshot displays the RFI interface. On the left, a sidebar contains links: Form, MSCs, Part I, Part II, Evaluation (highlighted in yellow), and Timetable. The main content area is titled 'Evaluation' and shows a list of RFIs. The first RFI, 'RFI 1', is highlighted. It has a status of 'Validation' and a due date of '11/03/2024' (highlighted in yellow). Below the RFI list, a table shows the 'Reason' as 'Incomplete' and a message: 'No changes have been made to the application.' The 'Response to consideration' section is also visible. It shows a 'Consideration number' of 'RFI-CT-2024-501856-32-00-IN-001-01' and an 'Application section parts' of 'Part I - Regulatory'. The 'Consideration' text is 'Please submit proof of payment'. Below this, there is a 'Response' section with a text input field (highlighted in yellow) and a 'Documents related to the response' section. At the bottom right, there are two buttons: 'Add document' and 'Save response' (highlighted in yellow).

RFI instructions for sponsors CONTINUED...

3. If changes to the application (new documents, modified documents, changes to the data fields) are requested in the RFI, then these can be applied via the 'Change application' button at the top-right corner of the RFI.

Please note: documents requested in the RFI should NOT be uploaded within the RFI itself. The two 'Add document' buttons are optional, and only serve to upload documents containing the RFI Response.

4. Clicking the 'Change application' button will lead you to the application, and unlocks the application for applying changes. The editing functionality will be activated, similar to when the application was first created. Close the lock of the section where changes need to be made, to allow changes to that section.

The screenshot shows the top section of an RFI application. At the top, the application ID is 'RFI-CT-2024-501856-32-00-IN-001' with a due date of '11/03/2024'. Below this, the application is identified as 'MSC: Netherlands' with a submission date of '28/02/2024' and a due date of '11/03/2024'. A yellow box highlights the 'Change application' button in the top right corner. The application status is 'Incomplete'. Under 'Supporting documentation', there are sections for 'Quality' and 'Non-Quality', both with a 'No document available' message. At the bottom, there are two 'Add document' buttons for 'General documentation' and 'Quality related documentation'.

The screenshot shows the 'Trial specific information (Part I)' section of the RFI application. On the left, there is a sidebar with a list of sections: 'Form', 'MSCs', 'Part I', 'Part II', 'Evaluation', and 'Timetable'. The 'Part I' section is highlighted in yellow. The main content area shows a list of trial details: 'Trial identifiers', 'Trial information', 'Protocol information', 'Scientific advice and Paediatric Investigation Plan (PIP)', and 'Associated clinical trials'. A yellow box highlights a lock icon in the top right corner of the 'Trial details' section, indicating that the section is currently locked for editing.

RFI instructions for sponsors CONTINUED...

5. The second symbol beside each document ( Edit) is used to edit the title, version or date of an existing document.

The third symbol ( Update) is used to upload a new version of that document. You will be asked to enter the new version number and document date.

The fifth symbol ( Add) only appears for documents in 'For Publication' slots and is used to upload the "Not for Publication" version of that document.

The blue 'Add document' button is used to upload new documents.

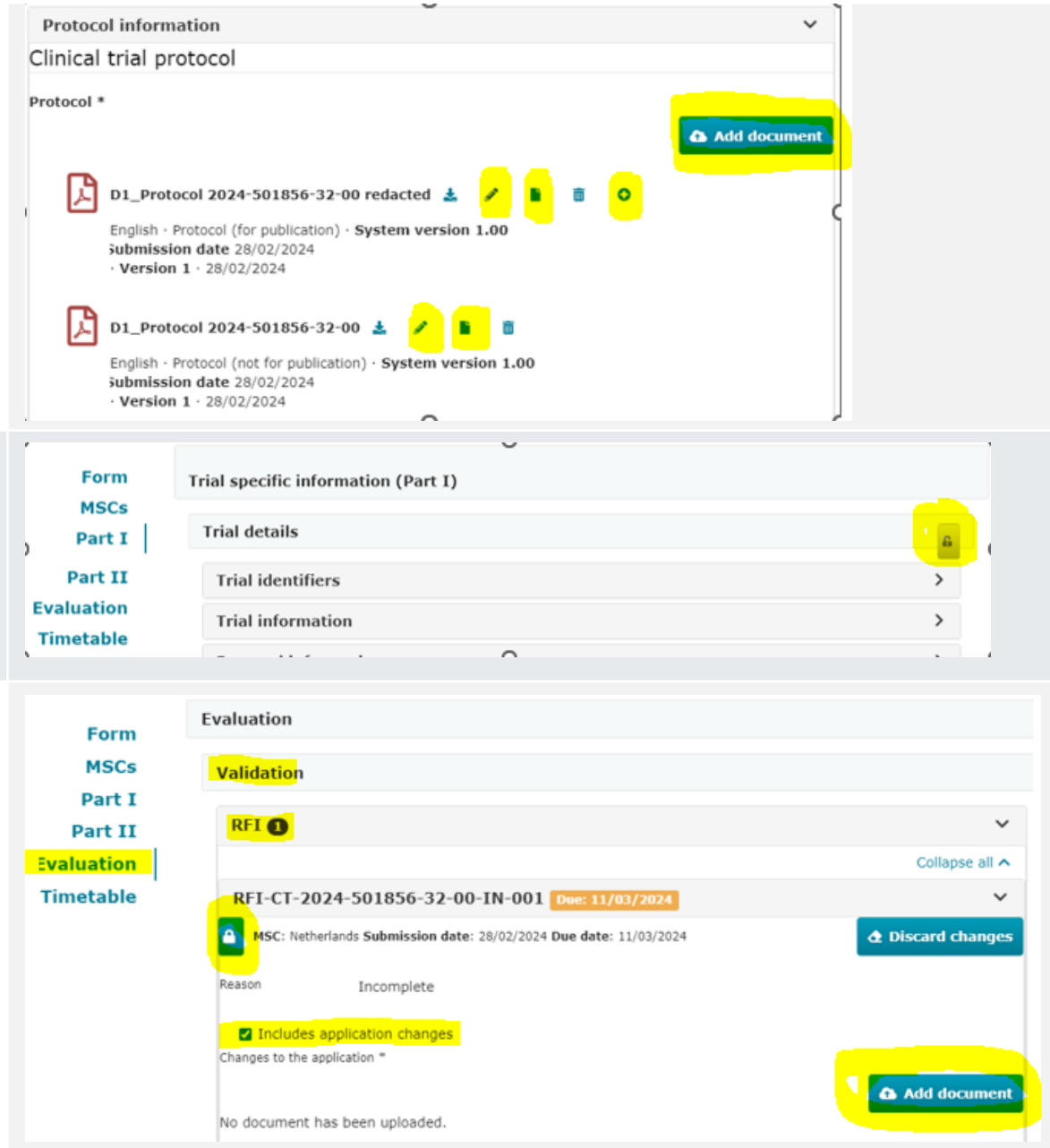
6. After all requested changes have been applied, open all locks again, and return to the evaluation environment by clicking 'Evaluation' on the left.

7. Navigate to the RFI that is being addressed, in this example this is the validation RFI. Click the lock again to close it.

Keep the box 'Includes application changes' checked.

A mandatory [RFI Response List of Changes to the Application document](#) should be uploaded via the 'Add document' button.

This document should describe all changes to the application in detail: provide a clear list of all new documents (title, version, date) and changes to data fields.



The screenshot displays the RFI interface with several key elements highlighted in yellow:

- Protocol information:** A dropdown menu showing 'Clinical trial protocol'.
- Protocol *:** A list of documents. The first document, 'D1_Protocol 2024-501856-32-00 redacted', has an 'Add document' button highlighted. The second document, 'D1_Protocol 2024-501856-32-00', has an 'Add document' button highlighted.
- Form:** A sidebar menu with 'Form', 'MSCs', 'Part I', 'Part II', 'Evaluation', and 'Timetable'. 'Evaluation' is highlighted.
- Trial specific information (Part I):** A section containing 'Trial details', 'Trial identifiers', and 'Trial information'. A lock icon is highlighted next to 'Trial details'.
- Evaluation:** A section containing 'Validation'. Under 'Validation', there is a list of RFIs. The first RFI, 'RFI-CT-2024-501856-32-00-IN-001', has a lock icon highlighted. Below the RFI list, there is a checkbox labeled 'Includes application changes' which is checked. A 'Discard changes' button is also visible.
- Add document:** A button at the bottom right of the page, highlighted.

RFI instructions for sponsors CONTINUED...

8. Finally, the RFI Response can only be submitted if:
- The RFI master lock in the top-left corner is closed, and
 - The list of changes document has been uploaded, and
 - A written response has been entered for all considerations, and
 - The locks of all individual considerations are opened.

The screenshot displays the RFI submission interface. At the top, the RFI ID is RFI-CT-2024-501856-32-00-IN-001, with a due date of 11/03/2024. The status is 'Incomplete'. A yellow box highlights the 'List of changes' document upload section, which includes a document icon, the text 'List of changes', and a 'Submit' button. Below this, the 'Consideration' section is visible, showing the consideration number RFI-CT-2024-501856-32-00-IN-001-03, the application section parts 'Part II - Netherlands', and the application section and document 'Subject information and informed consent form'. The consideration text is 'ICF pregnant partners is missing.' The sponsor response is 'ICF PP submitted.' The documents related to the response are listed as 'No document available'. A yellow box highlights the 'Submit response' button at the bottom right.

RFI 1

Collapse all ^

RFI-CT-2024-501856-32-00-IN-001 Due: 11/03/2024

MSC: Netherlands Submission date: 28/02/2024 Due date: 11/03/2024

Discard changes

Reason Incomplete

Includes application changes

Changes to the application **

Add document

List of changes

English · List of changes (for publication) · System version 1.00

Submission date 28/02/2024

Version 1 · 28/02/2024

Consideration number RFI-CT-2024-501856-32-00-IN-001-03 Application section parts Part II - Netherlands Application section and document Subject information and informed consent form

Consideration ICF pregnant partners is missing.

Sponsor response ICF PP submitted.

Documents related to the response

No document available

Submit response

Resubmission of an application

Resubmission

Applications that lapsed (sponsor misses RFI response deadline), were withdrawn by the sponsor, or received a negative validation (Not Valid) or a negative decision (Not Authorised), can be resubmitted.

On the clinical trial page, in the Summary tab, scroll down to the application overview. Click the application you want to resubmit.

The screenshot shows the 'Clinical trials' page with tabs for 'Clinical trials', 'Notices & alerts' (248), and 'Annual safety reports'. The 'Study title' section shows 'Not authorised' status, ID '2022-503500-25-00', and 'RMS: Netherlands'. The 'Summary' tab is selected and circled in red. A red arrow points down from the 'Summary' tab to the 'APPLICATION AND NON-SUBSTANTIAL MODIFICATION' section, with a box labeled '(Scroll down)'. Below this section is a table with columns 'Type', 'ID', and 'Parts'. The first row shows 'Initial' under 'Type', 'IN' under 'ID' (circled in red), and 'Part I & Part II' under 'Parts'.

Then, in the top-right corner, click Resubmit

The screenshot shows the application overview page. In the top-right corner, there are two buttons: 'Copy' and 'Resubmit'. The 'Resubmit' button is circled in red. The main content area is titled 'Trial specific information (Part I)' and contains a list of sections: 'Trial details', 'Trial identifiers', 'Trial information', 'Protocol information', 'Scientific advice and Paediatric Investigation Plan (PIP)', 'Associated clinical trials', 'References', and 'Countries outside the European Economic Area'. Each section has a right-pointing arrow.

The documents of the original submission will be copied to the resubmission. Documents can be replaced if necessary (e.g. cover letter). Please note: the version and date of all documents is reset to v1 and today, so click Edit (pencil icon) to enter the correct version and date for all documents. The resubmission will keep the original CT-number, but ending with -01.